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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,515	06/12/2001	Billy W. Colston	IL-10715	5330

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EXAMINER
TRAN, MY CHAU T

ART UNIT	PAPER NUMBER
1641	8

DATE MAILED: 08/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/880,515	COLSTON ET AL.	
	Examiner	Art Unit	
	My-Chau T. Tran	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 May 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *10-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 October 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group III (Claims 1-9) in Paper No. 7 is acknowledged.

The traversal is on the ground(s) that Group I (Claims 10-12) and Group II (Claims 13-28) should be rejoins because it should not be separated. Group III (Claims 1-9) and Group IV (Claims 29-35) should be rejoins because the search is not burdensome and the different operational steps establish different scope rather than different methods.

In regards with the restrictions between Groups I and II, this is not found persuasive in view of the discussion in paragraph 2 of the 5/15/02 Office Action in which the examiner clearly describes patentable distinctions among these inventions. Applicants have not addressed any errors in the reasoning set forth by the examiner in paragraph 2. Therefore, Group II is not rejoin with Group I.

Applicant's argument for rejoining Group III and Group IV was not found persuasive because the different operational steps do establish that they're different methods. As suggested by applicant that Groups III and IV have different scope, then the difference in scope indicate that they are different inventions (methods). Further, the search requirement is ***not*** co-extensive that a search for one invention would ***not encompass*** the limitations of the other inventions thus resulting in divergent of the search evaluations.

The requirement is still deemed proper and is therefore made **FINAL**.

2. Claims 10-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.

3. This application contains claims 10-35 are drawn to an invention nonelected with traverse in Paper No. 7. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Drawings

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "12" (pg. 11, line 5) and "33" (pg. 12, line 20) have both been used to designate microbeads. "25" (pg. 12, line 9) and "32" (pg. 12, lines 19- 20) have both been used to designate openings. "30" (pg. 12, lines 18-19) and "40" (pg. 12, line 23) have both been used to designate microbead capture array. "31" (pg. 12, line 19) and "51" (pg. 13, line 2) have both been used to designate substrate. "42" (pg. 12, line 24) and "53" (pg. 13, lines 3-4) have both been used to designate capture microbeads. "17" (pg. 11, line 12) and "26" (pg. 12, line 10) have both been used to designate disposable capture substrate. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "30" has been used to designate both indicator (pg. 12, line 14) and

microbead capture array (pg. 12, lines 18-19). "26" has been used to designate both disposable capture substrate (pg. 12, line 10) and substrate (pg. 12, line 12). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: "d' and e'" of figures 4-6; "11B" of figure 11A; "12B" of figure 12A. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) The method step of "containing optically encoded microbeads" of Claim 1 is vague and indefinite because it is just claiming that the microbeads is in a container. Therefore, it is unclear what the correlation of the microbeads being in a container and that of detecting the pathogen.

b) In Claim 1, "the targeted biological sample" of line 5 is inconsistent with what was previously recited, (i.e. "a sample") therefore the recitations lack an antecedent basis.

c) In Claim 1, "the target biological molecules" of lines 12-13 is inconsistent with what was previously recited, (i.e. "the targeted biological sample ") therefore the recitations lack an antecedent basis.

d) The method step of "attaching the microbeads" of Claim 1 is vague and indefinite because it is unclear how the microbead is attached. Although the specification has stated that there are various ways of attaching the microbeads to the solid support (pg. 14, lines 18-26 to pg. 15, lines 1-3). The claim does not clearly define which of these attaching methods are being claimed. Is the microbeads immobilized to a support? Is the microbeads being capture by using a filter? A magnetic?

e) It is unclear what the method steps are for the detection of the pathogen of Claims 2 and 7 since it is just claiming the type of container to hold the microbead. Since such a claim relates to the device and not the method of detection.

f) It is unclear what the method step is for the detection of the pathogen of Claim 3 since it is just claiming the holder vibrate when the microbeads are in the holder.

g) Claim 4 is vague and indefinite because "the dipstick" appears to lack antecedent support. This dipstick has not previously been defined before its use is recited.

h) Claim 5 is vague and indefinite because "the resolution" appears to lack antecedent support. This resolution has not previously been defined before its use is recited. How is this related to decoding the microbeads for identification and measuring the target biological molecules?

i) The term "unique assay" is vague and indefinite because it is unclear in what aspect of the assay is it consider unique. How is it unique? Is it the type of label use? Antibody?

j) It is unclear what the method steps are for the detection of the pathogen of Claims 9 since it is just claiming the type microbead. Since such a claim relates to the device and not the method of detection.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1-3, 5-7, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pyle et al. (US Patent 5,821,066).

Pyle teaches a method for the detection of microorganisms (col. 6, lines 48-50). The method steps are mixing the immunomagnetic beads that has bound antibody which specifically binds to the target bacteria with the liquid sample, placing the sample mixture in a magnetic separator to separate the beads from the liquid sample, washing the beads with a solution which removes loosely bound bacteria and other particles, and treating the bacteria that is conjugated to the beads with a specific fluorescent conjugated antibody, and mounting the sample for examination by epifluorescent microcopy (col. 12, lines 42-68; fig. 2). The sample is mounted by way of trapping the beads on a filter membrane and optically read (col. 14, lines 4-20). The method would also be use for detection of pathogenic bacterium (col. 16, lines 54-55). The beads are contained in a tube (cuvet), which is mounted for examination by epifluorescent microcopy (fig. 2; col. 17, lines 59-62; col. 18, lines 11-12). The method step of mounting the membrane for examination by epifluorescent microcopy in which suitable light filter system is used to excite fluorescent labeled in order to detect the present of the target microorganism (col. 10, lines 9-15). This would then provide the array pattern on such a membrane. The magnetic beads are obtained commercially, thus are package in a bead pack (col. 14, lines 1-3).

Pyle does not expressly disclose that the method step of adding the fluorescent labeled antibodies for attachment to the bead bound sample occurs before the method step of attaching the beads to a substrate.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method steps of Pyle by having the method step of adding the fluorescent labeled antibodies for attachment to the bead bound sample occurs before the method step of attaching the beads to a substrate. Because the order of the method steps would not change the result of the complex for detection that is a bead that has bound antibody which specifically binds to the target, which is then bound to a labeled antibody. Further, one having ordinary skill in the art would have been motivated to do this for the advantage of also washing off any unbound fluorescent labeled antibodies.

13. Claims 1, 4-6, and 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marshall (US Patent 5,236,826) in view of Okusa et al. (US Patent 4,952,520).

Marshall teaches a method for the detection of an analyte (col. 3, lines 19-45; col. 7, lines 23-45). The method steps are mixing the analyte with the particle-bound binding component and allowing them to react, adding a second binding component labeled with a signal-generating material to form an immunocomplex of particle-bound binding component:analyte:labeled binding component, separating the immunocomplex from the reaction mixture by a filtration procedure in which the filter material (substrate) retained the particle because of its size in the filter interstices (col. 7, lines 30-34), the complex is then washed to remove unbound labeled binding component, and the reaction area is read to measure the amount of signal present. The

analyte includes parasitic antigen (col. 6, lines 65-68). The particle includes bead (col. 4, lines 12-20). The label must be capable of emitting a signal such as fluorescent (col. 7, lines 7-22). Where enzymes labeling is use to produce a readable signal by a photometer with monochromatic light, by scanning the spectrum the instrument could distinguish the different wavelength signal (col. 8, lines 62-68), which would then provide the array pattern.

Marshall does not expressly disclose that the filter material (substrate) is on a dipstick.

Okusa teaches an immunoassay in which the colored latex particle are capture on a membrane that is attached to a test device (dipstick) (col. 2, lines 11-17; col. 4, lines 9-23; fig. 1 and 3).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to substitute the membrane in Marshall with the membrane attached to a dipstick taught by Okusa because both Marshall and Okusa teaches the method of capturing the analyte bound particle by filtration. The membrane system of Okusa would provide a compact bioanalytical filtering system to be use in an environment other than the laboratory.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 703-305-3399. The fax phone numbers for the

organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

mct
August 5, 2002

BAO-THUY L. NGUYEN
PRIMARY EXAMINER
8/6/02